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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,871	03/18/2004	Philip Russel James Smith	66347-104	5458
68804	7590	02/18/2009		
JOHN P. DE LUCA 17420 RYEFIELD CT. DICKERSON, MD 20842			EXAMINER RAMDHANIE, BOBBY	
			ART UNIT 1797	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/802,871	<b>Applicant(s)</b> SMITH ET AL.	
	<b>Examiner</b> BOBBY RAMDHANIE	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/04/2009 has been entered.

In a telephone interview with Mr. DeLuca on 02/10/09, Mr. Deluca clarified the status of the claims.

Claims 1-12 listed below are the active claims in the application and are the claims to be examined. Claims 13 & 14 are cancelled.

#### **LISTING OF CLAIMS:**

1. (Currently Amended) In combination a tube for storing micro-litre volumes and a multi-well plate having a bottom surface and through bores having a substantially square cross section extending through the plate to said bottom surface, said through bores for receiving one tube in a corresponding one of the through bores in said multi-well plate, the tube having first and second ends, the tube being open at the first end and adapted at the second end to engage the bottom surface of the multi-well plate, the tube comprising: a body portion of substantially square cross section corresponding to the cross section of the through bores; a shoulder portion near said one end of the body portion and providing the open end of the tube, the cross section of the shoulder portion

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being greater than that of the body portion; and a deformable formation having a cross section larger than the cross section of the bores providing a connector portion at the second end of the tube, said formation being deformable to fit through the through bore and to extend through the bottom surface to form a snap fit engagement with said bottom surface of the multi-well plate.

2. (Previously Presented) A tube according to claim 1, further comprising a closure member disposed to close the open end.

3. (Previously Presented) A tube according to claim 2, wherein the closure member comprises a foil cap.

4. (Previously Presented) A tube according to claim 2, wherein the closure member is a self-sealing member.

5. (Previously Presented) A tube according to claim 4, wherein the self-sealing closure member is a split septum.

6. (Previously Presented) A tube according to claim 1, wherein the body and shoulder portions are formed separately from the snap fit connector portion.

7. (Previously Presented) A tube according to claim 6, wherein the snap fit connector portion has a dot code on it.

8. (Previously Presented) A tube according to claim 6, wherein the body and shoulder portions are formed from a translucent or transparent material.

9. (Previously Presented) A tube according to claim 8, further comprising a spigot at the interface between the body portion and the snap fit connector portion.

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10. (Previously Presented) A tube according to claim 1, wherein the body portion and snap fit connector portion are co-moulded.

11. (Currently Amended) In combination a tube for storing fluid and a multi-well plate having a bottom surface and through bores having substantially square cross section extending through the plate to said bottom surface, said through bores for receiving one tube in a corresponding one of the through bores in said multi-well plate, the tube having first and second ends being open at the first end and adapted to engage the bottom surface of the multi-well plate, the tube comprising: a body portion of substantially square cross section corresponding to the cross section of the through bores, a shoulder portion near said first end of the body portion and providing the open end of the tube, the cross section of the shoulder portion being greater than that of the body portion; and a deformable flared connector portion at the second end of the tube having a cross section greater than the through bores and being deformable to fit through the through bore and to extend through the bottom surface to form a snap-fit engagement with the bottom surface of the multi-well plate. said flared connector portion having an identification code provided thereon.

12. (Previously Presented) A tube according to claim 11, wherein the connector and body portions are formed separately from different materials.

### ***Response to Arguments***

2. Applicant's arguments filed 02/04/2009 have been fully considered but they are not persuasive. Applicant is unclear where the confusion is in the claim language of the

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instant application. The Examiner would like to submit the following explanations and rejections in response to where the confusion lies.

3. Applicant's arguments with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection.

***Specification***

4. The abstract of the disclosure is objected to because there is no mention of a combination in the Specification. Correction is required. See MPEP § 608.01(b).

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the Examiner as to what the Applicants now claim as their invention because Applicants have amended the preamble of Claims 1 & 11 to be "In combination," however; the dependent claims are all to the tube by itself (Please see preamble of Claims 1-12). "In combination" renders the claims indefinite because it does not define the scope of the invention.

8. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention. Claims 1-12 recite the limitations "one end," "the open end," "the cross section," and "the through bore" in Claims 1 & 11. There is insufficient antecedent basis for these limitations in the claims.

9. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the Examiner if the through bores extend completely through the multi-well plate from the top surface to the bottom surface or only through a bottom surface of the multi-well plate.

10. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the Examiner if cross section being recited pertains to the length, width, or the diagonal cross section.

11. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The terms "adapted," "engage," substantially," "near," "corresponding," "deformable," and "flared" in claims 1-12, are relative terms which render the claim indefinite. The term "adapted," "engage," substantially," "near," "corresponding," "deformable," and "flared" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

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12. Claim 2 recites the limitation "the open end" in Claim 1. There is insufficient antecedent basis for this limitation in the claim.

13. Claims 2-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the Examiner how the additional limitation of a cap, foil cap, self-sealing member and split septum further define the structural limitations of the tube.

14. Claim 9 recites the limitation "the snap-fit connector portion" in Claim 1. There is insufficient antecedent basis for this limitation in the claim.

15. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants have amended the claims to now include a combination of a tube and a multi-well plate; however the Specification does not have support for this combination. Applicants have stated in the Specification that Figure 4 is **only an example of the present invention (See Page 4 line 17)**. This is not supportive of what the Applicants' allege as their invention. Drawings may not be used to overcome any insufficiency of the specification due to lack of an enabling disclosure or otherwise inadequate disclosure therein, or to supplement the original disclosure thereof for the purpose of interpretation of the scope of any claim. There is no mention of a combination of in the Specification.



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16. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants have amended the claims to now include a combination of a tube and a multi-well plate; however the Specification does not have support for this combination. The Specification does not support the new limitation of a tube wherein the body portion of substantially square cross section corresponding or corresponds to the cross section of the through bores.

17. Claims 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 contains a period followed by a final limitation. It is unclear to the Examiner whether this final limitation is part of the claim or was to be deleted. The Examiner will examine the claim as if the final limitation is part of the claim.

18. Claims 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the Examiner whether the bottom surface is on the tube or the multi-well plate in the preamble.

19. Claim 11 recites the limitation "the plate," "the through bore," and "said flared connector portion" in Claim 11. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

21. Claims 1 & 6-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Day (US20020098126).

22. Applicants' claims are toward **a tube**.

23. Regarding Claims 1 & 6-12, Day discloses the combination of a tube for storing micro-litre volumes and a multi-well plate having a bottom surface and through bores having a substantially square cross section extending through the plate to said bottom surface, said through bores for receiving one tube in a corresponding one of the through bores in said multi-well plate, the tube having first and second ends, the tube being open at the first end and adapted at the second end to engage the bottom surface of the multi-well plate, **the tube** comprising: A). A body portion of substantially square cross section corresponding to the cross section of the through bores (See [0089]); B). A shoulder portion near said one end of the body portion and providing the open end of the tube, the cross section of the shoulder portion being greater than that of the body portion (See Figure 13 & 14); and C). A deformable formation having a cross section larger than the cross section of the bores providing a connector portion at the second end of the tube, said formation being deformable to fit through the through bore and to

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extend through the bottom surface to form a snap fit engagement with said bottom surface of the multi-well plate (See Figure 2 Item 22; the Examiner interprets the limitation of forming a snap fit engagement with said bottom surface of the multi-well plate as an intended use limitation because the multi-well plate is not a positive recitation of the claim).

While there is no disclosure that the combination is a limitation as presently claimed, applicants attention is drawn to MPEP 2111.02 which states that "if the body of a claim fully and intrinsically sets forth all the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction". Further, MPEP 2111.02 states that statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the purpose or intended use results in a structural difference between the claimed invention and the prior art. Only if such structural difference exists, does the recitation serve to limit the claim. If the prior art structure is capable of performing the intended use, then it meets the claim.

It is the examiner's position that the preamble does not state any distinct definition of any of the claimed invention's limitations and further that the purpose or intended use, i.e. the combination of the tube and the multi-well plate, as recited in the present claims does not result in a structural difference between the presently claimed invention and

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the prior art of record and further that the prior art structure which is an equivalent and is identical to that set forth in the present claims is capable of performing the recited purpose or intended use of being fitted/sized/amended with the terms of degree listed in the 112 rejections to be used in a multi-well plate.

Additional Disclosures Included: Claim 6: **A tube** according to claim 1, wherein the body and shoulder portions are formed separately from the snap fit connector portion (See [0013-0019] & (See [0026-0028] & See Figure 2); Claim 7: **A tube** according to claim 6, wherein the snap fit connector portion has a dot code on it (See [0026-0028] & [0104]); Claim 8: **A tube** according to claim 6, wherein the body and shoulder portions are formed from a translucent or transparent material (See [0074]); Claim 9: **A tube** according to claim 8, further comprising a spigot at the interface between the body portion and the snap fit connector portion (See [0096] & See Figures); Claim 10: **A tube** according to claim 1, wherein the body portion and snap fit connector portion are co-moulded (See [0076] & Claim 22; The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)); Claim 11: In combination a tube for storing fluid and a multi-well plate having a bottom surface and through bores having substantially square cross section extending through the plate to said bottom surface, said through bores for receiving one tube in a corresponding one of the through bores in said multi-well plate, the tube having first and second ends being open at the first end and adapted to

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engage the bottom surface of the multi-well plate, **the tube** comprising: A). A body portion of substantially square cross section corresponding to the cross section of the through bores (See [0089]); B). A shoulder portion near said first end of the body portion and providing the open end of the tube, the cross section of the shoulder portion being greater than that of the body portion (See Figure 13 & 14); C). A deformable flared connector portion at the second end of the tube having a cross section greater than the through bores and being deformable to fit through the through bore and to extend through the bottom surface to form a snap-fit engagement with the bottom surface of the multi-well plate(See Figure 2 Item 22); and D). Said flared connector portion having an identification code provided thereon (See [0004], [0027-0033], & [0104]); and Claim 12: A tube according to claim 11, wherein the connector and body portions are formed separately from different materials (See [0074] & [0094]).

***Claim Rejections - 35 USC § 103***

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

25. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
26. Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Day in view of Helger et al, and Stanchfield et al.
27. Applicants' claims are toward **a tube**.
28. Regarding Claims 2-5, Day discloses the tube according to Claim 1, except for disclosing that the tube further comprises Claim 2: A closure member disposed to close the open end (See [0003]); Claim 3: The closure member comprises a foil cap; or Claim 4: The closure member is a self-sealing member; Claim 5: The self-sealing closure member is a split septum. Day does however disclose that cluster tubes in the prior art of record have caps or mats that seal the open end of the tubes (See [0003]). Helger et al teaches the closure member comprising a foil cap (Column 2 lines 30-50) and Stanchfield et al teaches the closure member comprising a self sealing member or split septum (Column 11 lines 25-40). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Day in view of Helger et al and Stanchfield et al because according to Helger et al, using a foil cap can be advantageous when the sample of interest needs to be freeze dried and must be sealed for preservation reasons, sample containers sealed with foil caps provide a very good seal, can withstand an internal pressure of 2 atm, and the foil can be removed or punctured to remove the sample at a later time (Column 4 lines 50-60 and Column 5 lines 0-5). According to Stanchfield et al, the rubber materials are chemical resistant and are well known for forming septa for sealing round bottom flasks and Erlenmeyer flasks and other containers commonly used by researchers (Column 11 lines 29-40).

***Telephonic Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BOBBY RAMDHANIE whose telephone number is (571)270-3240. The examiner can normally be reached on Mon-Fri 8-5 (Alt Fri off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. R./

/Walter D. Griffin/  
Supervisory Patent Examiner, Art Unit 1797